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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/083,122	05/22/98	MAJEED M	P8064-8009

HM12/0525
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EXAMINER

OH, T

ART UNIT PAPER NUMBER

1621

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DATE MAILED: 05/25/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
09/083,122

Applicant(s)

Majeed et al

Examiner

TAYLOR VICTOR OH

Group Art Unit

1621



☒ Responsive to communication(s) filed on the applicants' amendment dated on February 17, 1999.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-17 is/are pending in the application.

Of the above, claim(s) 3 and 4 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 2, and 5-17 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Response to Argument and Non-final rejection

1. The rejection of claim 5 under 35 U.S.C. 112, second paragraph is withdrawn due to the amendment made by the first office action
2. Applicant's arguments with respect to claims 1-2 and 5-17 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-2 and 5-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Y.S. Lewis (Methods in Enzymology; Vol XIII;1969; pages 615-616) in view of Lowenstein (U.S. 3,764,692).

Lewis discloses the preparation of the hygroscopic potassium salts of hydroxycitric acid in which the dried fruit rinds of *Garcinia cambogia* are cooked in water to be extracted with ethanol, after its filtration, 40% KOH is added to the acidic filtrate to neutralize the mixture, subsequently the oily liquid is washed repeatedly with ethanol, and finally the yellow semisolid is obtained from drying out the oily liquid in vacuo at 80° C.(see pages 615-616, method A).

However, Lewis does not teach the process involved in combining extracts at pH 10, refluxing the treated extract to obtain potassium hydroxy citrate, milling, sifting, blending, and packing the dried potassium hydroxycitric acid under nitrogen. In addition, the instant claims differ from Lewis in that the instant invention claims that the compound made by the process contains 33 to 38% of elemental potassium, has a specific rotation from (-) 20° to (-) 23°, and can be stable for 5 years under normal storage conditions.

Lowenstein teaches that the hydroxy citric acid (see col. 2, lines 1-4) may be obtained from the garcinia acid lactone by base hydrolysis with potassium hydroxide with heating followed by acidification (see col.1, lines 35-39). Furthermore, Lowenstein discloses that the garcinia acid is a strong inhibitor of citrate cleavage enzyme (see col.3, lines 31-32).

As for the percentage of elemental potassium, the specific rotation of the compound, and the long stability of the compound are naturally obtained as unique characteristics for evaluating the compound, not as the novelty of the invention.

Concerning milling, sifting, blending, and packing the dried potassium hydroxycitric acid under nitrogen, it is the well known practice in manufacturing the dried product in the industry to the one having an ordinary skill in the art.

With respect to combining extracts at pH 10, refluxing the treated extract to obtain potassium hydroxy citrate, it would have been quite obvious for the one with an ordinary skill in the art to extract the dried fruit rinds of *Garcinia cambogia* three times with ethanol to increase the quantity of the extracted material; furthermore, Lowenstein, the editor of Lewis' work, teaches that the hydroxy citric acid (see col. 2, lines 1-4) may be obtained from *Garcinia* by base hydrolysis, e.g., potassium hydroxide with heating followed by acidification, which is also meant that it would have been obvious for the one with an ordinary skill in the art to have used Lowenstein's process without acidification in order to produce the non-hygroscopic potassium salts of hydroxycitric acid. Therefore, it would have been obvious for the one with an ordinary skill in the art to combine Lewis' procedures with Lowenstein's teachings to produce the non-hygroscopic potassium salts of hydroxycitric acid.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Baniel et al. (U.S. 4,275,234) discloses a process for the extraction of acids from aqueous solutions, comprising an extraction operation in which a water-immiscible organic extractant

consisting of at least one secondary or tertiary amine , in which the number of carbon atoms is at least 20, or a mixture of two or more such amines, dissolved in a water-immiscible organic solvent, is mixed with the aqueous solution of the acid, the organic extract is removed from the residual aqueous liquid and, at a higher temperature than the temperature at which the extraction is performed, subjected to a stripping operation with an aqueous liquid for back-extracting at least a considerable amount of the acid from the organic extract into the water and isolating substantially all the amine in the organic phase; the aqueous back-extract is separated from the organic phase.

Guthrie et al (U.S. 3,767,678) describes the preparation of making ester and amide derivatives of threo-hydroxycitric acid γ -lactone by using an anhydrating agent defined as an agent that serves to convert a cis-1,2-dicarboxylic acid to the corresponding anhydride. Suitable anhydrating agents includes alkanic acid anhydrides, such as acetic anhydride, propionic anhydride; and alkanoyl halides, for example acetyl chloride. The anhydration reaction is suitably carried out at an elevated temperature in the range of 50° to 150° C.

Guthrie et al (U.S. 3,810,931) discloses the preparation of epoxyaconitic acid and esters useful for the control of lipogenesis. Epoxyaconitic acid may be prepared by epoxidation of aconitic acid. The epoxidizing agents include hydrogen peroxide and peracids like persulfuric acid. The epoxidation is preferably carried out in an organic solvent such as an alcohol or ether in the presence of an alkali metal salt at the temperature in the range of 0° to 100° C.

Ravi et al (FR 96-13094) describes a method of making magnesium(-)-hydroxycitrate useful in dietetics and in the cardiovascular field. Magnesium(-)-hydroxycitrate is prepared from

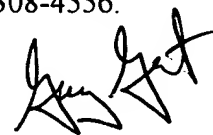
the reaction of the extract of *Garcinia cambogia* with ethyl alcohol in the presence of poly(vinylpyrrolidone). The crude product is filtered, agitated with an anion exchange resin and the final product is isolated after being dried.

Lawhon et al (U.S. 4,643,902) discloses a process of producing food juices by employing ultrafiltration. During the process, the UF retentate is treated to inactivate a sufficient number of spoilage microorganisms to inhibit spoilage of the juice under storage conditions, whereas the UF permeate can be treated by reverse osmosis to concentrate the flavor and aroma components. The concentrated flavor and aroma components can be recombined with the UF retentate for the other uses. The acid content of juice can be reduced by passing a portion of the RO retentate through an ion-exchange column.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Victor Oh whose telephone number is (703) 305-0809. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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5/20/99



GARY GEIST
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